100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106-2399 U.S.A.
TELEPHONE (215) 592-3000 CABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3377

(A)

8EHQ-97-13889 8EHQ-0297-13889s
88970000139

February 18, 1997

ROHM AND HAAS COMPANY

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

SANITIZED

COMPANY SANITIZED

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OPPT NSCD
97 FEB 18 AM 8:45

Dear Sir:

Rohm and Haas Company submits this notice in accordance with Section 8(e) of the Toxic Substances Control Act.

A two-generation reproductive toxicity study of [ ] is in progress. Dietary concentrations of [ ] in this study are 1000, 5000 and 20000 ppm active ingredient.

We have recently completed the lactation phase for the first generation of pups. There were no treatment-related effects on body weights of parental animals, mating or fertility parameters, numbers and survival of offspring, or growth of offspring through day 14 of lactation. However, treatment-related decreases in pup weight and spleen weight (both absolute and relative to body weight) at day 21 of lactation was observed at all dose levels. In the first mating, there was not a clear dose-response in the low and mid-dose groups. Therefore, the parental animals were remated to confirm the effects. The decreased pup weight was confirmed at all doses. Absolute spleen weight was also decreased in the second mating at all doses, but spleen weight relative to body weight was reduced at only the mid and high dose. Therefore, the relationship of the decreased spleen weight to reduced body weight is uncertain. Histopathological examination of the spleens will be performed to determine whether there is a specific target organ effect.

The decreased body weight occurs at a time when the pups are becoming less dependent on nursing, and beginning to consume the test diet directly. It is unclear whether the decreased body weight is due directly to [ ] toxicity (and increased sensitivity in immature animals) or secondary to decreased feed consumption related to irritation or decreased palatability. Indeed, during the premating phase of the P1 animals in this study, decreased palatability was indicated by a transient

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decrease in feed consumption (16%) in high dose females during the first week of treatment. Further studies are being planned to address this question.

[ ] is the Rohm and Haas experimental designation for [ ].
A diagram of the chemical structure is included in Attachment I.

Rohm and Haas has produced only small quantities of this new substance for exploratory testing purposes. Only a very limited number of highly trained laboratory personnel have been involved in the synthesis and testing of the substance. Appropriate safety procedures have been employed to preclude any exposure to new pesticidal candidates whose toxicological properties have not been fully defined. These employees have been advised of the results of these studies.

Because of this very low potential for exposure within the Rohm and Haas Company and the very low probability that this substance is in commerce elsewhere, Rohm and Haas Company does not believe that this exploratory chemical poses any substantial risk to health or the environment.

Rohm and Haas Company considers the exact identity of this chemical and its Rohm and Haas experimental designation number to be Confidential Business Information (CBI), and thus have enclosed with this letter a sanitized version for the public record with the confidential information deleted. We have also included, as Attachment II, substantiation supporting our CBI claims as required.

Rohm and Haas Company proposes the name "substituted benzamine" as a generic, non-confidential, chemical name to describe the chemical substance discussed in this notice.

If you have any questions concerning this submittal, my telephone number is (215) 592-2986.

Sincerely,

George J. Powell

George J. Powell
Senior Regulatory Specialist
Product Integrity Department

GJP:cdg
Enclosures

ATTACHMENT I

SANITIZED

[redacted]

Generic name: Substituted benzamine

TRIAGE of 8(e) Submissions

Date sent to triage: _____ (NON-CAP) CAP

Submission number: 13889 A TSCA Inventory: Y (N) D

STUDY TYPE (circle appropriate):

Ernest Falke (E605C)
ATOX SBTOX SEN CARC

Gordon Cash (E425)
ECO AQUATO

Katherine Anitole (E613B)
(RTOX) DTOX

Daljit Sawhney (E611A)
CTOX STOX

Deborah Norris (E606)
NEUR

Elizabeth Margosches (E613C)
EPI

Michael Cimino (E611D)
GTOX

Leonard Keifer (E611C)
Metabolism/Pharmacokinetics

OTHER: _____

NOTES:

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # HEHQ- 0297-13889S SEQ. A

TYPE: (INT. SUPP FLWP)

SUBMITTER NAME:
Rohm and Haas Company

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0539 REFER TO CHEMICAL SCREENING)
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0481 NO ACTION REPORTED
(0482 STUDIES PLANNED/UNDERWAY)
(0483 NOTIFICATION OF WORKERS/OTHERS)
0484 LABEL/MSDS CHANGES
0485 PROCESS/HANDLING CHANGES
0486 APPLICATION DISCONTINUED
0487 PRODUCTION DISCONTINUED
0488 CONFIDENTIAL

SUB. DATE: 2-18-97 [illegible] DATE: 2-25-97 CSRAD DATE: 5-6-97

CHEMICAL NAME:
~~Confident~~ Benzamine, substituted

CAS#
Confident

INFORMATION TYPE:		P	F	C
0201	ONCO (HUMAN)	01	02	04
0202	ONCO (ANIMAL)	01	02	04
0203	CELL TRANS (IN VITRO)	01	02	04
0204	MUTA (IN VITRO)	01	02	04
0205	MUTA (IN VIVO)	01	02	04
0206	REPRO/TERATO (HUMAN)	01	02	04
(0207)	REPRO/TERATO (ANIMAL)	(01)	02	04
0208	NEURO (HUMAN)	01	02	04
0209	NEURO (ANIMAL)	01	02	04
0210	ACUTE TOX. (HUMAN)	01	02	04
0211	CHR. TOX. (HUMAN)	01	02	04
0212	ACUTE TOX. (ANIMAL)	01	02	04
0213	SUB ACUTE TOX (ANIMAL)	01	02	04
0214	SUB CHRONIC TOX (ANIMAL)	01	02	04
0215	CHRONIC TOX (ANIMAL)	01	02	04

INFORMATION TYPE:		P	F	C
0216	EPI/CLIN	01	02	04
0217	HUMAN EXPOS (PROD CONTAM)	01	02	04
0218	HUMAN EXPOS (ACCIDENTAL)	01	02	04
0219	HUMAN EXPOS (MONITORING)	01	02	04
0220	ECO/AQUA TOX	01	02	04
0221	ENV. OCCC/REL/FATE	01	02	04
0222	EMER INCI OF ENV CONTAM	01	02	04
0223	RESPONSE REQEST DELAY	01	02	04
(0224)	PROD/COMP/CHEM ID	01	02	(04)
0225	REPORTING RATIONALE	01	02	04
0226	CONFIDENTIAL	01	02	04
0227	ALLERG (HUMAN)	01	02	04
0228	ALLERG (ANIMAL)	01	02	04
0239	METAB/PHARMACO (ANIMAL)	01	02	04
0240	METAB/PHARMACO (HUMAN)	01	02	04

INFORMATION TYPE:		P	F	C
0241	IMMUNO (ANIMAL)	01	02	04
0242	IMMUNO (HUMAN)	01	02	04
0243	CHEM/PHYS PROP	01	02	04
0244	CLASTO (IN VITRO)	01	02	04
0245	CLASTO (ANIMAL)	01	02	04
0246	CLASTO (HUMAN)	01	02	04
0247	DNA DAM/REPAIR	01	02	04
(0248)	PROD/USE/PROC	01	02	04
0251	MSDS	01	02	04
0299	OTHER	01	02	04

TRIAGE DATE:

NON-CBI INVENTORY
YES
CAS SR
(NO)
IN TERMINI

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RAT → ?

TOXICOLOGICAL CONCERN:
LOW
MED
HIGH

PRODUCTION:
[illegible]mental

COMMENTS:

SUBSTITUTED BENZAMINE

CONFIDENT

"13889A"="M"="ABSTRACT BASED ON SUMMARIZED RESULTS OF A STUDY IN PROGRESS SUBMITTED WITHOUT A REPORT. DIETARY CONCENTRATIONS OF 1000, 5000, AND 20000 PPM OF SUBSTITUTED BENZAMINE (CAS# CONFIDENT) WERE FED TO UN-NAMED ANIMALS AS PART OF AN ONGOING, 2-GENERATION REPRODUCTIVE STUDY. THERE WERE NO TREATMENT-RELATED EFFECTS ON BODY WEIGHTS OF PARENTAL ANIMALS, MATING OR FERTILITY PARAMETERS, NUMBERS AND SURVIVAL OF OFFSPRING, OR GROWTH OF OFFSPRING THROUGH DAY 14 OF LACTATION. TREATMENT-RELATED DECREASES IN PUP WEIGHT AND SPLEEN WEIGHT(BOTH ABSOLUTE AND RELATIVE TO BODY WEIGHT) AT DAY 21 OF LACTATION WERE OBSERVED AT ALL DOSES."